UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,456	09/19/2003	Douglas P. Cerretti	2517-D	5621

22932 7590 03/10/2006

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,456	CERRETTI, DOUGLAS P.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *12,13,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14-23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's Amendments to the specification and claims filed 21 December 2005 have been entered and claims 27-31 were canceled at Applicant's request. The amendments to pages 4, 43, and 47 of the specification were insufficient to overcome the objection of record to the specification, which is repeated below.

Objection to the Specification

The disclosure remains objected to because the removal of hyperlink suffixes only, e.g., "html", permits the specification to contain browser-executable code. Applicant is required to delete all instances of the prefixes, e.g., "www.", that permit the various web addresses at, e.g., pages 4, 43, and 47 to remain active as browser-executable code when the specification is viewed as a document on the Internet. See MPEP § 608.01. Appropriate correction is required.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, comprising the pending claims 1-11, 14-23 and 26 drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:12 in the reply filed on 21 December 2005 is acknowledged. There is no argument stating grounds of traversal in the reply of 21 December 2005, however, and the requirement is still deemed proper and is therefore made FINAL. Claims 12, 13, 24, and 25 are withdrawn from further consideration as drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11, 14-23 and 26 remain rejected for reasons of record under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed 21 December have been fully considered but they are not persuasive. Applicant suggests at pages 9-12 of the reply that a polypeptide comprising the disintegrin domain of SEQ ID NO:12 has a specific and substantial utility due to expression in a specific tissue, testis, as discussed in Example 4 at pages 48 and 49 of the specification and Figure 1. Figure 1 is not, however, an exhaustive set of tissues and, if it were, it would not provide a basis for a specific utility of the protein encoded by the transcript based on the presence of the included disintegrin domain, the amino acid sequence of which is the only structure required by each of the pending claims. There is no indication in the specification of the cellular or physiological function of the metalloprotease of SEQ ID NO:12 or of the cellular or physiological function of its included disintegrin domain. The utilities argued at pages 9-12 of the reply are not **specific** to the disintegrin domain within SEQ ID NO:12 as there is no indication that it can serve as a basis for specific identification of testis tissue or cells or whether its presence somewhere in the testis has any association with a normal or an abnormal physiological state, or an association with health or disease. The specification cannot identify any particular, i.e., specific, utility for the disintegrin domain within SEQ ID NO:12 among the many different functions established for some, but not all, disintegrin domains, "cell-to-cell adhesion, cell-to-matrix adhesion, and inflammatory responses", "prevent[ion of] platelet aggregation" and "anticoagulant" activity and there is no showing that disintegrins as a group are well-known to share a certain, specific, activity. Nothing in the specification indicates that Applicant was aware of any specific utility for the integral SVPH-1a metalloprotease of SEQ ID NO:12, or for its included disintegrin domain, which would permit its immediate use by the public at the time the application was filed. A method of using a material for further research to determine, e.g., its

specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The rejection of record is therefore sustained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 14-23 and 26 also remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph. Applicant's arguments filed 21 December have been fully considered but they are not persuasive. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The rejection of record is therefore sustained.

Claims 1, 3-10, 14-22 and 26 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 21 December have been fully considered but they are not persuasive. Applicant's arguments at pages 12 and 13 of the reply are directed to a proposed, but undemonstrated, function of the 103-amino acid sequence of a disintegrin domain at amino positions 389 through 491 of SEQ ID NO:12. The specification does not itself establish that the 103-amino acid sequence of a disintegrin domain at amino positions 389 through 491 of SEQ ID NO:12 has a role in either spermatogenesis or fertilization and, as noted above, fails to identify any specific function of the disintegrin domain. Thus the claim limitation "having disintegrin activity" is unsupported by the specification where the nature of the activity is undisclosed and is not demonstrated to

reside in the amino acid sequence region identified in claim 1. The arguments in the reply do not address the specification's failure to exemplify or describe the preparation of polypeptides that comprise the divergent amino acid sequences of claims 1, 3-10, 14-22, and 26-31 that are permitted by the claims to differ from the amino acid sequence set forth in SEQ ID NO:12 beyond the region identified in claim 1. Neither the claims nor the specification describe where amino acid differences may occur within SEQ ID NO:12 that permit a polypeptide to retain the undisclosed activity of the 103-amino acid sequence at amino positions 389 through 491 of SEQ ID NO:12 designated a disintegrin domain. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification furnishes no relevant identifying characteristics of polypeptides that differ from the amino acid sequence of SEQ ID NO:12 yet have "disintegrin activity", thus the rejection of record is sustained.

Claims 1, 3-10, 14-22 and 26 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, because the specification, while enabling the preparation of a polypeptide having the amino acid sequence of the elected SEQ ID NO:12, does not reasonably enable preparation of amino acid sequences having disintegrin activity that diverge from the amino acid sequence of SEQ ID NO:12 by unlimited amino acid substitutions, deletions and insertions, or combinations thereof anywhere within SEQ ID NO:12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 21 December that are directed to conservation of cysteine residues within, and relatively uniform sizes of, disintegrin domains have been fully considered but they are not persuasive. Yet claims 1, 3-10, 14-22 and 26 remain rejected for lack of enablement because they embrace unlimited, arbitrary, amino acid substitutions, additions or deletions anywhere, in any combination or pattern, within

SEQ ID NO:12 where the specification supports no insertions, deletions, or substitutions anywhere the SVPH-1a amino acid sequence SEQ ID NO:12 that permit the divergent products to retain the undisclosed disintegrin activity where neither the specification nor the prior art made of record, taken together, teach where any amino acid positions might be altered, nor the nature of the alterations that may be made, that permit a product with surrounding alterations to retain "disintegrin activity". As noted in the communication mailed 29 June 2005, the specification lacks adequate, specific, guidance for altering the SVPH-1a amino acid sequence of SEQ ID NO:12 to the extent permitted by the claims, and lacks working examples wherein the SVPH-1a amino acid sequence of SEQ ID NO:12 is altered to the extent recited in the claims. In addition, the state of the art and level of skill in the art do not support such alteration in view of the teachings of the prior art publications of record herein, thus unpredictability exists in the art where no members of the class of proteases represented by the amino acid sequence of SEQ ID NO:12 had even a few amino acid positions identified for concurrent modification. The rejection of record is therefore sustained.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 14-23 and 26 remain rejected for reasons of record under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 21 December alternatively alleging a role for a disclosed disintegrin domain within SEQ ID NO:12 in either spermatogenesis or fertilization have been fully considered but they are not persuasive. Claims 1, 6, and 15 remain indefinite in stating, "having disintegrin activity", because the specification contains no disclosure that identifies the alleged functions with the disclosed domain, nor does it disclose the nature of any particular "disintegrin" activity. Thus the artisan and the public seeking to

determine the metes and bounds of the intended subject matter cannot know what is covered by the claims. Because they depend from claims 1, 6 and 15 but do not otherwise resolve the ambiguity of the claims from which they depend, claims 2-5, 7-11, 14, 16-23 and 26 are included in this rejection of record, which is sustained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
3 March 2006

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER